IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	:	Attorney Docket No. 2006_0019A
Ryouichi HOSHINO et al.	:	**Confirmation No. 7559**
Serial No. 10/566,503	:	Group Art Unit 1618
Filed February 6, 2006	:	Examiner Nissa M. Westerberg
ORAL SUSTAINED-RELEASE TABLET	:	**Mail Stop: AMENDMENT**

REQUEST FOR RECONSIDERATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The following is responsive to the Office Action of June 16, 2009, the time for responding thereto being extended for three months in accordance with the extension fee submitted herewith.

Applicants submit the following remarks in support of the patentability of the presently claimed invention over the disclosures of the references relied upon by the Examiner in rejecting the claims. Further and favorable reconsideration is respectfully requested in view of these remarks.

Summary of Telephone Interview

Applicants kindly thank the Examiner for her willingness to discuss the above-identified application with Applicants' representative on August 6, 2009. During this interview, the double patenting rejection was discussed. The position of the Examiner is described in the discussion of the double patenting rejection, set forth below.

Double Patenting Rejection

Claims 3-5 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Application No. 11/795,792 in view of Alderman (U.S. Patent No. 4,734,285).

The co-pending application relied upon in the double patenting rejection (U.S. Application No. 11/795,792) was filed *after* the present application was filed. Applicants previously set forth arguments in this regard. (Please see page 5 of the response filed April 23, 2009.)

MPEP 804 (as relied upon in the previous response) indicates that the double patenting rejection should be withdrawn in the earlier filed application *if the double patenting rejection is the only rejection remaining in the earlier filed application*. In the above-identified application there is an additional outstanding rejection, i.e., the obviousness rejection discussed below.

During a telephone call with Applicants' representative, the Examiner confirmed that she will maintain the double patenting rejection until it is the only remaining rejection in the present application. In view of the comments and evidence provided herewith, the obviousness rejection should be withdrawn. Accordingly, the double patenting rejection will be the only remaining rejection in the above-identified application, and should accordingly be withdrawn.

Rejection Under 35 U.S.C. § 103(a)

Claims 3-5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Baichwal (U.S. Patent No. 5,399,359) in view of Miyachi et al. (Bioorganic & Medicinal Chemistry 1999) and Alderman (U.S. Patent No. 4,734,285).

The Position of the Examiner

The Examiner takes the position that Baichwal discloses solid oral sustained release formulations of oxybutynin, wherein controlled release of the active ingredient allows the desired blood levels of active ingredient to be maintained for a comparatively long period of time, while increasing patient compliance as fewer administrations are necessary. However, the Examiner admits that Baichwal fails to disclose Applicants' recited active agent (hereafter "KRP-197"), or HPMC.

The Examiner asserts that Miyachi et al. disclose that the inhibitory action of KRP-197 on bladder contractions is 15-19 times more potent of an inhibitor of bladder contractions than oxybutynin.

The Examiner also asserts that Alderman discloses that delayed release solid tablets can be prepared using HPMC.

The Examiner contends that it would have been obvious to a person of ordinary skill in the art to prepare a sustained release dosage form of KRP-197. Additionally, the Examiner contends that it would have been obvious to use HPMC with a viscosity of 4,000 cps as the controlled release agent, because Alderman teaches that HPMC of the recited viscosity can be used as a controlled release matrix for solid oral formulations.

Applicants' Arguments

This rejection is respectfully traversed for the following reasons.

Baichwal does describe controlled release oxybutynin formulations, and Miyachi et al. do describe that KRP-197 has stronger effects on the bladder than oxybutynin.

However, Applicants respectfully traverse the general and unsupported assertion that Applicants' invention may be easily achieved by merely applying the sustained-release technique disclosed in Alderman to the teachings of the other two references, i.e., the assertion that Applicants' invention is obvious based on the cited references.

Alderman discloses three sustained-release techniques, including (i) the direct compression method, (ii) the dry granulation method and (iii) the wet granulation method. When a very small amount of active ingredient is to be contained in such a sustained-release tablet as in Applicants' invention, it is remarkably difficult to make uniform pharmaceutical tablets by any of these disclosed methods. In order to demonstrate this assertion, Applicants have conducted several experiments, the results of which are presented in the enclosed Declaration under 37 CFR § 1.132.

The Examiner is respectfully requested to consider the experiments and results set forth in detail in the Declaration. These experiments demonstrate that the content uniformity of the tablets prepared in accordance with the prior art direct compression method, dry granulation method and wet granulation method were poor because of remarkable variations. On the

contrary, the content uniformity of the tablets prepared in accordance with the technique described in Example 5 of the above-identified application was favorable.

The fundamental problem to be solved by Applicants' invention is making appropriate sustained-release tablets containing a very small amount of KRP-197. Accordingly, even if the techniques as disclosed in Baichwal, Miyachi et al., and the like are well known, this fundamental problem cannot be achieved by merely applying the technique of Alderman to these known techniques. This is because Alderman does not disclose or suggest any essential feature of Applicants' invention.

For the reasons set forth above, as well as the evidence provided in the attached Declaration, it is evident that the subject matter of Applicants' claims is patentable over the cited combination of references. Thus, it is respectfully requested that the above-rejection be withdrawn.